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to: Mr. Philip L. Chao, Office of Policy, FDA
fax #: 301-443-6906
re: Proposed Foreign Establishment Registration and Listing: Comments from Quebec Medical Device Industry Association (AQFIM)
date: July 26, 1999
pages: 4, including this cover sheet.

You may recall that we spoke on the morning of Friday, July 23.

I had undertaken last week, when I returned from holidays and learned about the May 14 proposal for Foregn Establishment Registration and Listing, to ensure that the various relevant industry associations were aware of the proposal and the brief time remaining for comment.

The Quebec medical device industry association, *Association québécoise des fabricants de l'industrie médicale* (AQFIM) has sent their comments to me and asked that I forward them to appropriate officials.

cc: Birgit Matthiesen, Canadian Embassy, Washington, Fax: 202-682-7726
David Shortall, DFAIT/EAS, Fax: 613-943-0346/944-0756

From the desk of...

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Without Prejudice

Ms Linda Leinan
Gouvernement du Canada
Ottawa (Ontario)

Subject : US Designated Agent

Dear Linda,

Your recent request addressed to AQFIM regarding the above mentioned topic has been referred to me as the newly elected President of the Association.

Therefore, please find attached a brief summary of our actual position onto this important matter.

Would these comments be forwarded or addressed directly to any other parties, please advise accordingly,

Kindest Regards,

Dr Jacques R. Marcotte
Predident

JRM/lp

Enclosure

TOPIC :

New proposed regulation from FDA
Ref. US designated agent

N.B. : "Designated Agent" herein referred to as "Agent",
- and -
Food and Drug Administration, herein referred to as "Agency"

OBJECTIVES :

1. Requirement to foreign establishments to register with FDA.
2. and to appoint an Agent...

COMMENTS :

In reference to # 1 hereabove :

As long as the procedure does not create important differences from US-companies, we agree with the ruling.

To # 2. This proposed rule should "assist FDA... that devices are not adulterated or misbranded and are safe and effective..."

On one hand, it is appropriate to delete any duties of the Agent regarding :
a) the annual certification
b) the pre-notification (510K).

On the other hand, althouth FDA solicits comments from the industry to seek who may best perform the Agent duties, we disagree with the nomination of such "third party" who would act on behalf of foreign manufacturers.

At this point, it is not a question of seeking who's best at performing but to re-examine and revise the impact on the industry of such decision.

AQFIM represents predominantly a number of small entrepreneurs whom financial capacity to export is very precarious.

The important additional costs associated with the nomination of such agent have been underestimated by the Agency.

Larger corporations enjoy a presence in USA through an established distribution network, either through partnerships with otner major corporations or via domestic sales representation or US subsidiaries. These entities are therefore much less vulnerable to this new regulation.

For most (if not all) smaller organizations, there is actually no US representation, no agent, no residency...

As already underlined by FDA, it is difficult to find individuals willing to take on the duties of an Agent and their fees being too high...

In addition, the Agent through sound contractual agreement would probably never acept to be bound legally on behalf of the foreign manufacturer. The legal aspect has probably not been examined throughly.

In addition to Agent fees would be the "Insurance coverage" which would represent an additional financial burden to manufacturers !

For a product to be safe and effective, all standards, procedures, quality systems manufacturing procedures, clinical evaluation, etc. have been under the scrutiny and confidential information of the company. A third party such as the Agent would not be in a position to respond adequately to government's inquisitions...

This new ruling would only help the Agency to lower its operating costs while transferring more responsibilities and inherent costs to the industry.

When FDA states that it included the US designated agent in December 1995 final rule in order to assure that foreign and domestic manufacturers are treated equally... it is quite questionable since the designation of a US Agent is not mandatory to US organizations !

In conclusion, we recognize that it is certainly difficult for the Agency to assess the economical impact when ruling is addressed to foreign compagnies. A further delay would be necessary to allow such manufacturing entities to complete an in-depth review to measure the economical impact of such decision.

In a worst scenario, a similar ruling could be limited to foreign manufacturers of Class III and/or Class IV devices, where safety and effectiveness are closely associated with a higher risk to patients.

Finally, since Canada has adopted a new sets of regulations being effective as per July 1998, our government is working in cooperation with other countries for multilateral agreements leading to a potential mutual recognition of standards and approvals...

Would this particular problem of the US agent become effective, it might be just a question of time to see a similar reaction from other countries adding more difficulties and costs to our local manufacturers for their export sales.